K081380

510(k) SUMMARY
for the
Cayman Thoracolumbar Plate System

NOV 19 2008

This safety and effectiveness summary for the Cayman Thoracolumbar Plate System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

1. Submitter :
K2M, Inc.
751 Miller Drive SE,
Suite F1
Leesburg, VA 20175

Contact Person :
Richard W. Woods
K2M, Inc.
751 Miller Drive SE, Suite F1
Leesburg, VA 20175
Telephone: 703-777-3155

Date Prepared: May 13, 2008

2. Tradename: Cayman Thoracolumbar Plate System
Common Name: Thoracolumbar Plates
Classification Name: Spinal intervertebral body fixation orthosis (21 CFR 888.3060)

3. Predicate or legally marketed devices which are substantially equivalent :

- Blackstone Medical Unity Anterior Lumbar Plate Fixation System
- Synthes Thoracolumbar Spine Locking Plate
- Medtronic Sofamor Danek Pyramid Anterior Plate Fixation System
- Sofamor Danek Z-Plate

4. Description of the device:

The Cayman Thoracolumbar Plate System is a spinal fixation system which consists of screws and plates. All of the components are available in a variety of sizes to match more closely the patient's anatomy.

Materials: The devices are manufactured from CP Titanium and Ti6Al4V per ASTM and ISO standards.

Function: The system functions as an adjunct to fusion to provide immobilization and stabilization of the spine.

5. Intended Use:

The Cayman Thoracolumbar Plate System is indicated for use via the lateral or anterolateral surgical approach in the treatment of thoracic and thoracolumbar (T1-L5) spine and for use as an anteriorly placed supplemental fixation device for the lumbosacral level below the bifurcation of the vascular structures. When properly used this system will help provide temporary stabilization until a solid spinal fusion develops. Specific indications include: a) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), b) pseudoarthrosis, c) spondylolysis, d) spondylolisthesis, e) fracture, f) neoplastic disease, g) unsuccessful previous fusion surgery, h) lordotic deformities of the spine, i) idiopathic thoracolumbar or lumbar scoliosis, j) deformity (i.e., scoliosis, kyphosis, and/or lordosis) associated with deficient posterior elements such as that resulting from laminectomy, spina bifida, or myelomenigocele, k) neuromuscular deformity (i.e., scoliosis, lordosis, and/or kyphosis) associated with pelvic obliquity.

6. Technological and Performance Characteristics:

The Cayman Thoracolumbar Plates were tested in static compression bending, dynamic compression testing and static torsion in accordance with ASTM F1717 and are considered substantially equivalent to other legally marketed devices. They are similar in design, material, and indications for use and are expected to be equivalent in safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

K2M, Inc.
% Mr. Richard W. Woods
Senior VP, Engineering
751 Miller Drive, Southeast, Suite F1
Leesburg, Virginia 20175

NOV 19 2008

Re: K081380
Trade/Device Name: Cayman Thoracolumbar Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis.
Regulatory Class: II
Product Code: KWQ
Dated: November 07, 2008
Received: November 13, 2008

Dear Mr. Woods:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081380

Indications for Use

510(k) Number (if known):

Device Name: Cayman Thoracolumbar Plate System

Indications for Use:
The Cayman Thoracolumbar Plate System is indicated for use via the lateral or anterolateral surgical approach in the treatment of thoracic and thoracolumbar (T1-L5) spine and for use as an anteriorly placed supplemental fixation device for the lumbosacral level below the bifurcation of the vascular structures. When properly used this system will help provide temporary stabilization until a solid spinal fusion develops. Specific indications include: a) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), b) pseudoarthrosis, c) spondylolysis, d) spondylolisthesis, e) fracture, f) neoplastic disease, g) unsuccessful previous fusion surgery, h) lordotic deformities of the spine, i) idiopathic thoracolumbar or lumbar scoliosis, j) deformity (i.e., scoliosis, kyphosis, and/or lordosis) associated with deficient posterior elements such as that resulting from laminectomy, spina bifida, or myelomenigocele, k) neuromuscular deformity (i.e., scoliosis, lordosis, and/or kyphosis) associated with pelvic obliquity.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-the-counter Use __ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS-LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative, and Neurological Devices

510(k) Number K081380